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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,997	12/15/2000	James G. Keck	14- 020210US	5984

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EXAMINER	
EPPS, JANET L	

ART UNIT	PAPER NUMBER
1635	17

DATE MAILED: 01/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/601,997	KECK ET AL.	
	Examiner	Art Unit	
	Janet L Epps-Ford, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-14 and 58-69* is/are pending in the application.

4a) Of the above claim(s) *58-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10,15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 58-69 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicants have elected group II, claims 8-14, without traverse, and have cancelled claims 1-7 and 15-57. Therefore, since claims 58-69 all depend from claim 1, drawn to a non-elected invention, claims 58-69 are also drawn to a non-elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 58-69 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Applicant's election without traverse of Group II, claim(s) 8-14, in Paper No. 16 is acknowledged.

Claim Objections

3. Claim 8 is objected to because of the following informalities: Claim 8 recites "step, , obtaining." A comma is incorrectly duplicated in this phrase. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "altered function(s)" in claims 8-14 is a relative term that renders the claim indefinite. The term "altered function(s)" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 8-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Beach et al. (US Patent 6,255,071)

Claims 8-14 are drawn to a method of assigning a function to a product coded for by a sample nucleotide sequence, said method comprising (a) without any intervening bacterial cloning steps, obtaining and expressing one or more members of an oligonucleotide as a transcription product in recombinant non-bacterial host cells, wherein: the coding sequences for each individual transcription product encodes an antisense nucleic acid that, when expressed as RNA binds to mRNA transcribed from a target nucleic acid molecule that comprises a nucleotide sequence of the sample nucleic acid; and expression of one or more of the individual transcription products inhibits production of a product of the mRNA; b) analyzing phenotypic changes in the resulting host cells to thereby identify one or more altered function(s); and c) obtaining a nucleotide sequence of said target nucleic acid, whereby, based upon the altered function, a function is assigned to a sample nucleotide sequence.

The invention of Beach et al. include, but are not limited to, methods for the identification and isolation of nucleic acid molecules based upon their ability to complement a mammalian cellular phenotype, antisense-based methods for the identification and isolation of nucleic acid sequences which inhibit the function of a mammalian gene, gene trapping methods for the identification and isolation of mammalian genes which are modulated in response to specific stimuli (col. 3, lines 14-25).

The Beach et al. invention also includes antisense methods for gene cloning which can include a method for identifying new nucleic acid sequences based upon the observation that loss of an unknown gene produces a particular phenotype, and can comprise, for example, (a) infecting a cell with a retrovirus derived from a GSE-producing retroviral vector containing a test nucleic acid sequence, or, alternatively, transfecting such a cell with a vector of the invention

containing a test nucleic acid sequence, wherein, upon infection, an integrated provirus is formed, or, depending on the vector, an episomal sequence is established, and the test nucleic acid is expressed; and (b) assaying the infected cell for a change in the phenotype, so that new nucleic acid sequences may be isolated based upon the observation that loss of an unknown gene produces a particular phenotype(col. 24, lines 17-34).

In one particular example, Beach et al. teach an in vitro screen for genes that can induce telomerase activity in normal human mammary epithelial cells (HMEC). In this method, pools of cDNAs comprising from 100--100 clones each (either in the sense orientation or in the *antisense orientation* in the MaRXIIg vector series) are introduced into HMEC cells. These are selected for expression of cDNA and then used to prepare lysates for the assay of telomerase activity. Cell lysates are tested using a highly sensitive telomerase assay, which is capable of detecting two telomerase-positive cells among 20,000 telomerase-negative cells. Those pools which upon infection cause the induction of telomerase activity in HMEC cells are subdivided into smaller pools. Sub-pools are again used for the infection of HMEC cells which are subsequently assayed for telomerase activity. Successive rounds of this procedure can identify an individual clone that acts as an inducer of the telomerase enzyme. Such a clone could represent a direct regulator of the enzyme itself or of the expression of a component of the enzyme. Alternatively, such a clone could act as a regulator of cell mortality. Changes induced by the expression of such a clone could induce the telomerase enzyme as only one aspect of a more global change in cellular behavior (col 48, line 54, to col. 49, line 20). In the case where the cDNA is introduced in antisense orientation (see col. 48, line 66), it is possible that the expression of this antisense construct produces a transcript in and of itself functions as an inducer that inhibits the ability of a

suppressor of telomerase enzyme activity. Therefore in this example, alteration of gene function is associated with the expression of or the level of synthesis of the telomerase enzyme, which is a normal physiological and biological function associated with mammalian cells.

Beach et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE
January 7, 2003

SEAN McGARRY
PRIMARY EXAMINER